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### Transcatheter Coil Embolization of Congenital Coronary Artery Fistulae

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We describe our experience with nonsurgical closure of coronary artery fistulae (CAF) using a transcatheter approach and Gianturco coils. Since 7/92 6 patients (pts) age 9 to 22 years (mean = 14.5) were referred for evaluation and treatment of CAF. Two were symptomatic with chest pain and a third had dyspnea on exertion. Catheterization was performed from the femoral region using IV sedation in 5, and general anesthesia in 1. Selective coronary angiograms were performed in all pts followed by hand or power injections within the fistulas themselves. Angled views were employed to detail fistula anatomy as well as to visualize coronary artery branches. Catheters were manipulated into each fistula from a retrograde aortic approach. Temporary balloon occlusion of the fistula with EKG monitoring was performed in 5. Coils were placed through an end hole catheter positioned distally within the fistula.

Each pt had a single fistula. Two CAF arose from the LAD: 1 drained into the RV and 1 into the RA. One CAF arose from the circumflex artery and drained into the RV. Three CAF arose from the RCA: 2 drained into the RA and 1 into the RV. Temporary balloon occlusion in one pt resulted in significant ST segment changes and aided in the identification of the origin of the posterior descending artery adjacent to the fistulous connection to the RV. Coil embolization was not attempted in this pt. The remaining 5 pts underwent successful complete occlusion of the CAF using multiple (2 to 16) Gianturco coils. There were 2 coil embolizations to the pulmonary artery with successful retrieval of 1. At follow-up (1-15 months, mean = 11) all pts are asymptomatic with no clinical or echocardiographic evidence of recanalization or residual shunts. Transcatheter closure is the preferred method to safely and effectively close most CAF.

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### Catheter Management of Stenotic Fontan Baffles & Conduits

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Fontan conduit or baffle stenosis may lead to elevated right sided pressures, poor exercise tolerance, chronic effusions and/or atrial arrhythmias (AA). Since these findings may also occur independently post Fontan, we report a group of 14 patients who underwent balloon dilation (BD) and/or stent placement (SP) of stenotic Fontan conduits or baffles.

From 1/87 to 6/94, 18 procedures (10/18 SP; 8/18 BD) were performed in 14 patients (pts) with Fontan baffle or conduit stenosis, aged 1.3 to 39.4 years (21.6 ± 11.8 y). Diagnoses were tricuspid atresia (12/14), single ventricle (1/14) and malaligned complete atrioventricular canal (1/14). The previous Fontan procedures included a right atrium (RA) to pulmonary artery (PA) conduit in 11, atriopulmonary anastomosis (APA) in 2 and a lateral tunnel (LT) Fontan in 1. All pts had decreased cardiac index (CI) and poor exercise tolerance; 7/14 had AA; 1/14 had chronic effusions. At catheterization, 4 pts underwent BD only. Ten pts had 13 iliac stents (30 mm) placed (12 in conduits and 1 in a stenotic APA). The balloon/vessel ratio was  $3.0 \pm 1.2$ . There was no mortality with the procedure. One pt died 1.6 y later following conversion to a LT Fontan. Complications were AA requiring cardioversion (3/14), migration of a stent to the RA (1/14) which was retrieved in the cath lab and misplacement of a stent in the proximal left PA. Following BD and/or SP: 1) mean vessel diameter increased from  $7.4 \text{ mm} \pm 3.6 \text{ mm}$  to  $11.7 \pm 4.4$  ( $p < 0.01$ ); 2) the mean gradient at stenotic baffle or conduit changed from  $7.9 \pm 6 \text{ mmHg}$  to  $2.6 \text{ mmHg} \pm 3.39$  ( $p < 0.005$ ); 3) the mixed venous saturation changed from  $51\% \pm 11$  to  $59\% \pm 12$  ( $p < 0.01$ ); 4) mean RA pressures changed from  $20 \pm 6 \text{ mmHg}$  to  $16.6 \pm 4$  ( $p < 0.01$ ); 5) CI changed from  $1.8 \pm 0.6 \text{ l/min/m}^2$  to  $2.5 \pm 1.1 \text{ l/min/m}^2$  ( $p < 0.06$ ). At follow up (1.3 ± 1.1 y) 4 pts had no symptomatic improvement and underwent conduit change (1), conversion to a LT (2) and Fontan take-down (1). Eight pts had symptomatic improvement, with 2/14 lost to follow-up.

**Conclusion:** BD and/or stent placement of stenotic Fontan baffles or conduits improves hemodynamics and often provides short term symptomatic benefit.

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### Stent Implantation for Relief of Branch Pulmonary Artery Stenosis: Immediate and Short-term Results

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Stent implantation to relieve branch pulmonary artery stenosis (BPAS) is an alternative to failed surgical or balloon angioplasty. From April 1992 to August 1994, 26 patients underwent an attempt at stent implantation (11 in Boston; group 1 and 15 in Riyadh; group 2). The two groups median age was 7.6

years (range 1.3 - 64 years). 20/26 were post surgical repair of tetralogy of Fallot, two patients after Fontan operation, two with native BPAS, and one each with Williams syndrome and Alagille syndrome. A total of 37 stents were implanted successfully in 25 patients (16 in group 1 and 21 in group 2). The systolic gradient across the stenosis fell from a median of  $40 \pm 22$  to  $9 \pm 6 \text{ mmHg}$ ,  $p < 0.001$  and the diameter of the narrowest segment improved from  $4.7 \pm 0.4$  to  $10.8 \pm 0.4 \text{ mm}$ ,  $p < 0.001$ . The right ventricle to aortic pressure ratio fell from 0.68 to 0.49,  $p < 0.001$ . The median fluoroscopy time was  $150 \pm 20$  minutes. Complications included 2 patients where the balloon ruptured prior to full stent inflation, one stent was positioned in the superior vena cava and the other in the inferior vena cava. No other complications. Quantitative lung perfusion scan was performed pre and post stent deployment in 9 patients. This showed significant improvement of pulmonary blood flow in patients receiving unilateral stent. Patients were maintained on aspirin alone in group 1 and aspirin with dipyridamole in group 2. 10 patients underwent repeat cardiac catheterization at a mean follow-up interval of 15 months. The gradient across the stent remained low at  $20 \pm 4 \text{ mmHg}$  and there was no change in the diameter ( $11 \pm 0.5 \text{ mm}$ ). One patient developed significant restenosis secondary to intimal proliferation at the stent site, this was redilated successfully. We conclude that balloon expandable stents are safe and effective in relieving BPAS. Stents should be considered the treatment of choice for most patients with BPAS.

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### Biological Response to Appropriately Placed Bard Clamshell Septal Occluder Devices in the Canine Heart

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The Bard Clamshell Septal Occluder Device has been used to close various congenital defects. Little is known about the long term biological response to device placement. The original Bard Clamshell® Septal Occluder Device (OD) has been revised to decrease the risk of arm fractures. This study evaluates and compares the long term response to placement of the new Bard Clamshell II Septal Occluder Device (BSO) and the OD. Twenty three dogs underwent blade atrial septostomy followed by balloon dilation. A 23 mm device was deployed 2 weeks later to close the ASD. Dogs were evaluated angiographically at 1 month, 3 month, 6 month, 1 year and 2 year intervals. A portion of the dogs were sacrificed at each of these intervals. Explant x-rays, gross and microscopic evaluation were then performed on the excised heart. Ten dogs underwent placement of the OD, and thirteen dogs the BSO. In the OD group, 1/10 dogs had an arm fracture between 3 and 6 months after placement. In the BSO group, 0/13 dogs had arm fractures. There was no evidence of thrombus formation in either group on angiographic follow-up or pathologic evaluation. By one month, in both groups, the device was at least 50% endothelialized with a normal healing response. Scanning electron microscopy (SEM) showed neointima formation with an endothelialized surface. There was generally a focal foreign body reaction with macrophages and foreign body giant cells at the tissue/device interface. Focal areas of capillary formation in developing granulation tissue were seen within the fibrosed edges of the device, and were secondary to a rigid device within moving tissue. The device was completely endothelialized by 3 months. At six months, there was normal healing in both groups. In the OD group, microscopic calcium deposition was noted in 2/2 dogs sacrificed at one year. Gross evaluation on the two year OD dogs showed normal healing. One year and two year dogs in the BSO group (3/3 each) are awaiting sacrifice. In both groups, SEM indicated no evidence of metal corrosion or fatigue. In conclusion, appropriately placed Clamshell Occluder devices are well tolerated up to 2 years in the canine heart with complete endothelialization by 3 months post-implantation. There are no significant differences up to 6 months in the healing response between the old and new device designs. The new devices have not fractured to date.

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### Restenosis After Pulmonary Artery Angioplasty

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The expanding role of combined catheter and surgical therapies for complex congenital cardiac defects has led to wider application of pulmonary artery (PA) angioplasty. However remarkably little information is available on the fate of previously dilated pulmonary arteries. We undertook this study to determine the frequency and predictability of restenosis after PA angioplasty.

All PA dilations performed from 1/90 to 12/93 at Children's Hospital were reviewed to determine initial success (a.  $\geq 50\%$  increase in stenosis diameter; b.  $> 20\%$  decrease in the ratio of right ventricular to aortic pressure (intact ventricular septum); or c.  $\geq 20\%$  increase in lung perfusion). Initial and followup up catheterization data for successful dilations (based on angiographic criteria only) were then reviewed to determine patient age and diagnosis; etiology of stenosis; balloon size, type, inflation pressure; complications; and diameters of the stenosis and distal vessel pre and post dila-